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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,528	12/15/1999	SAVERIO CARL FALCO	BB1205-US-NA	7694

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/22/2002

SL

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/464,528

Applicant(s)

FALCO ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on RCE filed 3/1/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 1, 2002, has been entered.

Claims 1 and 7 are newly amended.

Claims 1-11 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-7 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed July 5, 2001.

Applicant's arguments filed March 1, 2002, have been fully considered but they are not persuasive.

Claims 1-11 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid fragment comprising a promoter

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that is SEQ ID NO: 6, and an isolated nucleic acid fragment comprising a promoter that is SEQ ID NO: 14, does not reasonably provide enablement for an isolated nucleic acid fragment comprising a promoter having at least 80% identity with any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15, or 16, or a promoter which hybridizes with any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15, or 16. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed July 5, 2001.

Applicant's arguments filed March 1, 2002, have been fully considered but they are not persuasive.

Applicant argues that the cited reference of Benfey et al. does not teach or suggest that sequence homology cannot be used to identify other promoters, because Benfey et al. is directed to recombining the subdomains of the CaMV 35S promoter in order to analyze the effect of the recombined subdomains on tissue specific gene expression. Applicant points out that the instant invention is concerned with an isolated nucleic acid fragment comprising a promoter having at least 80% identity with, or which hybridizes to, any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15 or 16, and not toward recombining subdomains in order to confer tissue specific gene expression, as taught in the cited reference of Benfey et al. Applicant also argues that the cited reference of Kim et al. does not teach or suggest that sequence homology cannot be used to identify other promoters because Kim et al. is directed to the abolishment of promoter activity by deletion or site specific mutagenesis of specific nucleotides within the promoter.

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Additionally, Applicant points to the Declaration of Dr. Zhongsen Li under 37 CFR § 1.132, showing that the DNA fragment of SEQ ID NO:14 functions as a promoter in transgenic plant cells. Applicant also points to Example 4, page 19, lines 9-31, describing a method to obtain sequences similar to the SAMS promoter using a fragment corresponding to SEQ ID NOS: 6, 14, 15 or 16 as a hybridization probe, to Example 5, page 21, describing a method of constructing an expression cassette containing a SAMS promoter 5' to a GUS reporter gene, to Example 5, page 21, describing a method of stably transforming *Arabidopsis* with such an expression cassette, to Example 5, page 22, describing the details of a histochemical GUS staining assay, and the details of a fluorometric assay for GUS activity, and Applicant asserts that these techniques are well known to those of ordinary skill in the art, and that no undue experimentation is required for those of ordinary skill in the art to practice these techniques. Applicant argues that in light of these teachings there is no lack of written description.

Applicant further argues that the rejection under 35 U.S.C. 112, first paragraph, for scope of enablement, should also be withdrawn in light of the same arguments set forth in response to the written description rejection.

Regarding the cited references, the Examiner maintains that it is not pertinent whether or not sequence homology can be used to identify other promoters. The claimed invention is not drawn to methods of identifying promoters on the basis of sequence homology. The claimed invention is drawn to an isolated nucleic acid fragment comprising a promoter having at least 80% identity with, or which hybridizes to, any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15 or 16. The Examiner maintains that both Benfey et al. and Kim et al. are pertinent

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to the written description and scope of enablement rejections under 35 U.S.C. 112, first paragraph, in that both references teach that promoters having a high degree of structural homology may or may not have functional homology. Accordingly, the Examiner maintains that sequence homology alone is not sufficient to describe a functional promoter, or to enable promoter function.

Regarding the Declaration of Dr. Zhongsen Li, the declaration supports the description and enablement of a promoter that is SEQ ID NO:14, because the declaration discloses that SEQ ID NO:14 is able to drive the expression of two reporter genes, GUS and the SU resistant mutant ALS gene. The declaration does not support the description or enablement of isolated nucleic acid fragments comprising a promoter having at least 80% identity with, or which hybridize to, any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15 or 16, because the declaration does not disclose any isolated nucleic acid fragment comprising a promoter having at least 80% identity with, or which hybridizes to, any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15 or 16.

Regarding Examples 4 and 5 of the specification, the Examiner agrees that the techniques described are well known to those of ordinary skill in the art, and that no undue experimentation is required for those of ordinary skill in the art to practice these techniques. However, the claimed invention is not drawn to a method to obtain sequences similar to the SAMS promoter by hybridization, or to a method of constructing an expression cassette, or to plant transformation methods, or to assay methods for the detection of the product of a GUS reporter gene. The claimed invention is drawn to an isolated nucleic acid fragment comprising a promoter having at least 80% identity with, or which hybridizes to, any of the nucleotide sequences set forth in SEQ

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ID NOS: 6, 14, 15 or 16. The Examiner maintains that Applicant has not described any nucleic fragments having promoter activity that have at least 80% identity with, or that hybridize to, any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15 or 16. The Examiner also maintains that the specification does not provide sufficient guidance for one of skill in the art to determine, without undue experimentation, which of these nucleotide sequences would have promoter function if tested with a reporter gene in an expression construct. Many nucleic fragments would have at least 80% identity with, or would hybridize to, any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15 or 16. Some of these fragments would have promoter function and others would not. The specification does not disclose sufficient structural information relevant to promoter function for one skilled in the art to know on the basis on structure which of the many sequences claimed would be likely to have promoter function. The lack of guidance and undue experimentation reside in the selecting of sequences for testing, rather than in the methods of testing themselves.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

May 13, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800

Elizabeth F. McElwain